REMARKS/ARGUMENTS

I. Status of the Claims

Claims 1-16, 18-21, 29-33 are withdrawn

Claims 17, 22 and 27 are amended

Claims 17, 22-28 are pending

II. Pending claims overcome 35 U.S.C. §112 rejections

Amended claims 17 and 27 overcome 35 U.S.C. §112 first paragraph and second paragraph rejections respectively. Therefore, claims dependent claims from claims 17 and 27 also overcome the 112 rejections that the examiner mentioned on pages 3-6. Claim 27 is amended to include SEQ ID NOS as requested by the examiner. Support for amendments to claim 27 can be found on page 14, Table 3 of the specification.

III. U.S. Pat. No. 5,583,046 (Valenta *et al.*,) and Vrtala *et al.*, do not anticipate the pending claims

On page 6 of the Action, the examiner rejected claims 17 and 22-28 under 35 U.S.C. §102 (b) as being anticipated by U.S. Pat. No. 5,583,046, as evidenced by Vrtala *et al.* The examiner has not established a legally sufficient basis for 102 (b) rejection.

To anticipate, **a single reference must teach all the elements** of the claims. *RCA Corp v. Applied Digital Data Sys., Inc.*, 221 USPQ 385, 388 (Fed. Cir. 1984). An anticipating prior art reference should disclose **each and every limitation** of the claim expressly or inherently. *Akamai Techs. v. Cable & Wireless Internet Servs.*, 344 F.3d 1186, 1192 (Fed. Cir. 2003). To anticipate a claim, a reference must **disclose every element of the challenged claim and enable** one skilled in the art to make the anticipating subject matter. *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996). (emphases added)

The examiner appears to combine the '046 patent, which does not even mention polymer or multimeric profilin with Vrtala *et al.*, which states that polymerization decreases allergenicity (discussed below). Such a combination is an improper and an incorrect basis for an anticipation rejection and even if combined, the combination still does not teach all the elements of the

pending claims.

The '046 patent does not disclose all the claim elements. For example, '046 does not disclose or even suggest the use of a multimeric profilin to hyposensitize a mammal. The '046 merely discloses a synthetic version of a 14 kDa birch pollen antigen P14.

> The present invention provides **recombinant DNA molecules** which contain a nucleotide sequence that codes for a polypeptide which exhibits the same or similar antigenic properties as a natural allergen, P14,...(Col. 2, lns. 14-17)
>
> The present invention covers the use of **P14 synthetic polypeptide** allergens to hyposensitize or desensitize a mammal. Such polypeptides can be administered to a human subject either alone or in combination with pharmaceutically acceptable carriers or diluents, in accordance with standard pharmaceutical practice. (Col. 11, lns. 34-40)

In contrast, the claims of the present application are based, in part, on the increased IgE recognition of profilin multimers. Polymers or multimers are based on, or derived from, the original, native (or recombinant) whole *polymeric* molecule. Singular fragments based on the sequence that uniquely may arise, or be exposed, upon profilin polymerization that are not available in the monomeric parent molecules. This may reflect one or more novel amino acid sequences that are comprised of part of each of at least two monomers complexed together to form the polymer, or a sequence that is buried within the tertiary monomeric structure that becomes exposed upon multimerization with one or more additional profilins. Such fragments are not dependent upon whether a portion of IgE epitope(s) is present or not. The novel polymers of the present invention takes advantage of native configurations/structural phenomenon that lead to the pan-allergenic potential (not taught in the '046 patent) that, in turn, may be used to develop a diagnostic and therapeutic use to induce a hypoallergenic response with vaccine therapy.

Vrtala teaches against the present invention. For example, on page 914, left column, Vrtala states the following:

> It could be shown that rBet v2 formed polymers through disulfide bonds, and it is hence suggested that the **decreased allergenicity of rBet v 2 might be related to its tendency to polymerize**. (emphasis added)

On page 920, left column, Vrtala further states the following:

> [a]nd it is hence possible that the **weaker capacity** of rBet v 2 to induce IgE antibodies might be linked to the ability to form natural **polymers through disulfide bonds**. Although it must be stressed that there is currently no feasible experimental data suggesting that polymerization of antigens might be a mechanism with which to reduce the allergenicity of protein antigens in favor of a TH1 response. (emphasis added)

Therefore, Vrtala further illustrates contrasting conclusions to the present invention about the use of profilin multimers in diagnostics and therapeutics. The utility of profilin polymers was not recognized nor was it obvious that the profilin polymers would be a key allergen.

The examiner rejected claim 25 over Vrtala et al., because the examiner believes that "Bet v2 would inherently have novel sequences that arise from polymerization..." on page 6 of the Action.

Inherency cannot be based on the knowledge of the inventor; facts asserted to be inherent in the prior art must be shown by evidence from the prior art. *In re Debizak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). When anticipation is based on inherency of limitations not expressly disclosed in the assertedly anticipating reference, as the examiner admits in the present case, it must be shown the undisclosed information was known to be present in the subject matter of the reference. *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 2002 U.S. App LEXIS 18007, *15, (Fed. Cir. 2002); *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749-50 (Fed. Cir. 1991).

In the present case, there is no evidence in Vrtala that synthetic peptide fragments derived from multimeric profilin have novel sequences that arise from profilin multimerization and are useful for hyposensitization. A finding of inherency cannot be made unless it is shown that the undisclosed information, in this case, the use of multimeric profilin to hyposensitize, was "known to be present in the subject matter of the reference."

An inherent limitation is one that is necessarily present; invalidation based on inherency is not established by "probabilities or possibilities." 2002 U.S. App LEXIS at *15; *Scaltech, Inc. v. Retec/Tetra, LLC.*, 178 F.3d 1378, 1384, 51 USPQ2d 1055, 1059 (Fed. Cir. 1999) and that is all the examiner presents. The purpose of the rule of inherency is to accommodate common knowledge, knowledge that judges might not know but that would be known to practitioners in the field. 2002 U.S. App LEXIS 18007 at *18; *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d

1354, 1365, 51 USPQ2d 1001, 1009 (Fed. Cir. 1999). "If the [prior art] limitation is inherently disclosed... it must be necessarily present and a person of ordinary skill in the art would recognize its presence." *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1377; *In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed Cir. 1999). To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Finnigan Corporation, v. U.S. Int'l Trade Comm'n*, 180 F.3d 1354 (Fed. Cir. 1999).

IV. Other issues

A sequence listing is submitted along with this response pursuant to 37 C.F.R. 1.821. Claim 22 is amended to include a period in the end.

No fees are believed due at this time, however, please charge any additional deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our docket number (21511/92177).

Respectfully submitted,

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